DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2005

Hwadong International Company Limited
C/O Ms. Marian Cochran
Atico International USA, Incorporated
501 South Andrews Avenue
Ft. Lauderdale, Florida 33301

Re: K023662
Trade/Device Name: Prosonic™ Ultraviolet Toothbrush Sanitizer
Regulation Number: 21 CFR 872.6855
Regulation Name: Manual Toothbrush
Regulatory Class: I
Product Code: MCF
Dated: February 25, 2003
Received: March 5, 2003

Dear Ms. Cochran:

This letter corrects our substantially equivalent letter of May 28, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

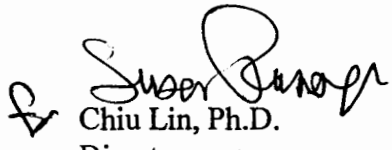
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 023662

MAY 28 2003

VIII. Safety and Effectiveness Summary

Submitter:

Hwadong International Company, Ltd.
#298-12, Kongse-Ri
Kieheung-Eup,.Yongin-City
Kyungki-Do
Korea

Official Correspondent:

Marian Harding Cochran, Esq.
Atico International USA, Inc.
501 S. Andrews Avenue
Ft. Lauderdale, FL 33301
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Date Summary Prepared: October 10, 2002

Device Trade Name: proSonic™ Ultraviolet Toothbrush Sanitizer

Device Common Name: Ultraviolet Toothbrush Sanitizer

Predicate Device: Purebrush Ultraviolet Toothbrush Sanitizer (Purebrush Associates)

Summary of Device Description:

The proSonic Ultraviolet Toothbrush Sanitizer unit sanitizes toothbrushes hung inside the unit by reducing the amount of bacteria that accrues on them under normal conditions of use. Sanitization is accomplished via ultraviolet (UV) radiation produced by a UV lamp housed within the unit. When activated, the proSonic Ultraviolet Toothbrush Sanitizer completes an initial sanitization cycle in one (1) hour. Afterwards, a built-in timer in the unit alternately causes the UV lamp to be turned off for sixty (60) minutes and turned on for five (5) minutes in between brushing cycles. Depending on usage, the UV lamp will typically be activated for approximately one hundred-sixty five (165) minutes per day. The bulb has an effective life of ten thousand (10,000) hours. The sanitizer is designed so that the UV lamp can be activated only when the unit door is fully closed, and the level of ozone emitted by the sanitizer is within FDA regulatory limits. The proSonic Ultraviolet Toothbrush Sanitizer is sold with four (4) accompanying toothbrushes and a power handgrip (which converts the toothbrushes into powered toothbrushes).

Intended Use:

The proSonic Ultraviolet Toothbrush Sanitizer is intended for use in reducing bacterial contamination that naturally accrues on toothbrushes under normal conditions of use.

Substantial Equivalence Comparison:

The proSonic Ultraviolet Toothbrush Sanitizer is substantially equivalent to the Purebrush Ultraviolet Toothbrush Sanitizer. The intended use of both devices is identical - to reduce bacterial contamination that accrues on toothbrushes under normal conditions of use. [Both devices are substantially equivalent in terms of materials and design.] Additionally, the technological characteristics of both devices are substantially equivalent. Both the proSonic and the Purebrush sanitizers use ultraviolet light to reduce bacterial contamination. Both devices house a UV lamp that effectively eliminates most bacteria on toothbrushes stored therein. Ozone emissions for the two devices are similar and comply with acceptable FDA regulatory limits. The UV lamps in both devices cannot be activated unless the units are fully closed. The wavelengths emitted by the UV bulbs in the two devices are also substantially equivalent. Additionally, although their sanitization cycle lengths and the lifetimes of their respective UV bulbs are different, these differences are not significant to the safety or effectiveness of the proSonic device. Like the Purebrush, the proSonic UV toothbrush sanitizer is safe and effective for toothbrush sanitization.

Summary of Performance Testing:

Laboratory and actual use tests were conducted to demonstrate the effectiveness of the proSonic Ultraviolet Toothbrush Sanitizer in reducing bacterial contamination on toothbrushes, as well as the extent to which the device emits ozone. These tests demonstrate that bacterial contamination on toothbrushes is significantly reduced by the device and that the ozone emitted by this product is minimal and within limits specified at 21 C.F.R. § 801.415 (2002).

Conclusion:

Based on the comparison of features of the proSonic and Purebrush UV sanitizers and the performance testing discussed above, it is concluded that the proSonic Ultraviolet Toothbrush Sanitizer is as safe, as effective, and performs as well as or better than the Purebrush Predicate Device for the intended use of reducing bacterial contamination on toothbrushes, and is thus substantially equivalent thereto.

Indications for Use Statement

510(k) Number (if known): K023662

Device Name: Prosonic™ Ultraviolet Toothbrush Sanitizer

Indications for Use:

The Prosonic™ Ultraviolet Toothbrush Sanitizer is intended for use in reducing bacterial contamination that naturally accrues on toothbrushes under in-use conditions.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ (Per 21 CFR 801.109) **OR** **Over-the-Counter Use** _XX_ (Optional Format 1)

Dr. Robt. Beltz DDS for Dr K. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023662